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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/894,921	06/28/2001	Udit Batra	20243CA	1812

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EXAMINER	
SHARAREH, SHAHNAM J	

ART UNIT	PAPER NUMBER
1617	10

DATE MAILED: 06/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/894,921	Applicant(s) BATRA ET AL.	
	Examiner Shahnam Sharareh	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 March 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16 and 24-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16, 24-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Amendment filed on March 18, 2003 has been entered. Claims 1-16, 24-44 are pending. Any rejection that is not addressed in this Office Action is considered obviated in view of the claim Amendments.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1-16, 24-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Makooi in view of Remington: the Science and Practice of Pharmacy 19th edition (pages 1616-1620) (IDS, filed June 28, 2001) and Christ et al US Patent 5,874,430.

3. Applicant's arguments have been fully considered but are not found persuasive. Applicant primarily argues that Makooi does not teach the instantly claimed superdisintegrant amounts of 1-5% in his tablet formulations and therefore Applicant asserts that the combination of the cited references do not teach or suggest the claimed invention.

In setting forth the arguments, Applicant essentially ignores the general knowledge available to one of ordinary skill in the art of formulation pharmaceutics. In response the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re*

Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the general knowledge available to one of ordinary skill in the art, the nature of the art and the combined teachings of Makooi, Remington and Christ meets the legal test of obviousness. Thus, Examiner maintains that the prima facia case of obviousness has been properly established.

As recognized by the Applicant the essential difference between Makooi's compressed tablets and the instantly claimed tablets is in the amount of superdisintegrants employed. The instantly claimed tablets are otherwise identical to those taught in Makooi. Examiner acknowledges that Makooi's efavirenz tablet contains disintegrates in amount of 10% or greater, but the instant efavirenz tablets contains from 1-5% of superdisintegrants. Nevertheless, the general knowledge available in the art would as recognized by the Applicant and taught by Makooi provides ample expectation of success when superdisintegrants are used in amount of 1-10% by weight relative to the total weight of the dosage unit. Further, contrary to Applicant's assertion in page 7, para 4, nowhere does in Makooi suggests that a low level of superdisintegrant is inappropriate for efavirenz's formulations. In fact efavirenz capsules use just such amounts of superdisintegrants. Therefore, optimizing the superdisintegrant amounts in Makooi's formulations would have been well within purview of an ordinary artisan at the time of invention.

Furthermore, it is well established that merely selecting proportions and ranges is not patentable absent a showing of criticality. In re Becket, 33 USPQ. 33 (C.C.P.A.

1937). In re Russell,439 F.2nd 1228, 169 U.S.P.Q. 426 (C.C.P.A. 1971). Accordingly, absence the showing of criticality, it would have been *prima facie* obvious to optimize the superdisintegrant amounts in the efavirenz formulation of Makooi' by routine experimentation. Moreover, Applicant has not provided any evidence of unexpected results or showing of criticality for the lower concentrations of superdisintegrants. Thus, the rejection is hereby maintained.

Applicant also argues that Christ does not teach efavirenz formulations. However, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the instant case, the combined teachings of Makooi, Remington and Christ renders the claims prima facia obvious. Nevertheless, with respect to Christ, Examiner states that at minimum Christ discloses efavirenz like crystalline compounds that can be prepared into pharmaceutical tablets comprising acceptable ingredients selected from a group consisting of filler/disintegrants such as lactose, binder such as starch, lubricant such as magnesium stearate, surfactant such as silicon dioxide.

Thus, even though Makooi may not exemplify the instant superdisintegrant concentrations or the use of hydroxypropylcellulose as the binder of choice, it would have been obvious to one of ordinary skilled in the art of dosage formulation to optimize the individual ingredients of Makooi's dosage forms by routine experimentation and

further substitute any suitable art equivalent moiety known in the art such as hydroxypropylcellulose.

Conclusion

4. No claims are allowed. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 703-306-5400. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 703-308-1877. The fax phone numbers for the organization where this application or proceeding is assigned

are 703-308-4556 for regular communications and 703-308-4556 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

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RUSSELL TRAVERS
PRIMARY EXAMINER
GROUP 1200